MAY 2 6 2000

510(k) Summary for Behring Coagulation System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K000973

1. Manufacture's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:	Dade Behring Marburg GmbH Emil-von-Behring Str. 76 Marburg/Germany
Contact Information:	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Rebecca S. Ayash
Preparation date:	March 24. 2000

2. Device Name/ Classification:

Behring Coagulation System:	Multipurpose system for *in vitro* Coagulation studies
Classification Number:	Class II (864.5400)

3. Identification of the Legally Marketed Device:

Sysmex® CA 6000 (K964139)

4. Device Description:
The current BCS was determined to be substantially equivalent as a fully automated photometric coagulation analyzer in 510(k) Premarket Notifications K970431 and K992959. The current BCS was cleared to perform coagulometric, chromogenic and immunochemical tests, such as the routine tests prothrombin time, partial thromboplastin time, heparin, and fibrinogen, as well as the special tests, single factor determination, antithrombin IIIa, batroxibin, D-dimer, plasminogen, protein C, and von Willebrand factor. The inclusion of the new testing parameter, derived fibrinogen, is the subject of this modification. The addition of the new proposed analyte to the instrument was accomplished without modification to the instrument principle, operation or hardware.

5. Device Intended Use:
The Behring Coagulation System performs quantitative assays of specific parameters in human citrated plasma.

6. Medical device to which equivalence is claimed and comparison information:
The Behring Coagulation System is substantially equivalent in intended use and results obtained to the Sysmex® CA 6000, which was the subject of 510(k) K964139. Both instruments use light at various wavelengths for the measurement of several coagulation assays.

7. Device Performance Characteristics:

Correlation:
The modified BCS comparison study evaluated 164 plasma samples ranging from 1.3 to 12.3 g/l on BCS with the Dade® Innovin® (derived fibrinogen) versus Dade® Innovin® (derived fibrinogen) on the Sysmex® CA 6000. A correlation coefficient of 0.972 was obtained, with a y-intercept value of –0.09 and a slope of 1.06.

Precision:
Precision studies were performed by the evaluation of two levels of control material and two levels of human plasma pools in a manner consistent with NCCLS Guideline EP5-A. The inter-assay precision ranged from 1.5 to 3.7%, while the intra-assay precision ranged from 3.7 to 4.5%.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 6 2000

Ms. Rebecca S. Ayash
Manager, Regulatory Affairs, Biology
Dade Behring, Inc.
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714

Re: K000973
Trade Name: Behring Coagulation System
Regulatory Class: II
Product Code: JPA
Dated: March 24, 2000
Received: March 27, 2000

Dear Ms. Ayash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K000973

Indications Statement

Device Name: Behring Coagulation System

Indications for Use:

The Behring Coagulation System (BCS) is an automated coagulation analyzer for *in vitro* diagnostic use in clinical laboratories. The instrument performs the following parameters:

- Prothrombin Time (PT)
- Activated Partial Thromboplastin Time (APTT)
- Antithrombin IIIa
- Batroxibin
- D-dimer
- Deficient Plasmas
- Derived Fibrinogen
- Fibrinogen
- Heparin
- Plasminogen
- Protein C-clotting
- Protein C-chromogenic
- Thrombin Time
- von Willebrand factor

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter L. Maglione

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000973

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter-Use _
(Optional Format 1-2-96)